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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,818	03/19/2004	Patrick A. Tresco	MICI 1019458	7091
27111	7590	04/07/2006	EXAMINER	
GORDON & REES LLP 101 WEST BROADWAY SUITE 1600 SAN DIEGO, CA 92101			GRAY, PHILLIP A	
			ART UNIT	PAPER NUMBER
			3767	

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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Office Action Summary	Application No. 10/804,818	Applicant(s) TRESKO ET AL.	
	Examiner Phillip Gray	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 03 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4,6-8,10-14,18,22-24,26-28,30-32 are rejected under 35 U.S.C. 102(b) as being anticipated by Moenning (U.S. Patent Application Number 2002/0193734). Moenning discloses a device for implanting biological moieties in a host (see figures 4-6), comprising: a tube bound by an isolating jacket (86,92); a conduit bound by a casing.

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(12) which defines a lumen therein mounted between the proximal and distal ends of said tube (see figure 7); and a chamber within said tube defined by said jacket and said casing (50), and a support positioned between said conduit and said semi-permeable jacket and disposed for engaging an interior surface of the jacket with a helical shaft (30) and a bore (66) formed the length of the shaft. The Moenning device discloses a jacket and casing comprises an elastomer selected from the group consisting of silicon and the jacket is biocompatible (paragraph 80). Moenning discloses that medium comprises solutes comprising biological moieties is disposed in said chamber, said lumen, or said chamber and lumen wherein solutes diffusively transport between said lumen, said chamber, and said bloodstream (see figure 8). Further Moenning discloses a seal (222,226) covering a lumen which is rigid to resist kinking of the device upon insertion into and travel in a peripheral blood vessel. See figures 1-11, 24,25)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation

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under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 5 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moenning. Moenning discloses the claimed invention except for the surface of the jacket comprises anti-thrombotic material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the surface of the jacket comprising anti-thrombotic material, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 227 F.2d 197, 125 USPQ 416 (CCPA 1960). Since this device is going into blood vessels it would be obvious to make it of a biocompatible, non reactive substance, non-clotting substance.

Claims 9 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moenning. Moenning discloses the claimed invention except for explicitly disclosing a lumen sized for over-the-wire insertion in a blood vessel. It would have been obvious to one having ordinary skill in the art at the time the invention was made to make a lumen sized for over-the-wire insertion in a blood vessel since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 USPQ 237 (CCPA 1955).

Claims 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moenning in view of Gaskill (U.S. Patent Number 4,911,717). Moenning discloses the claimed invention except for the lumen connected to a flexible implantable injection port and catheter. Gaskill teaches that it is known to use the lumen connected to a flexible implantable injection port and catheter as set forth in paragraphs beginning at columns 4 through 6, to provide an internal access point to the device conduit. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the delivery device as taught by Moenning with the lumen connected to a flexible implantable injection port and catheter as taught by Gaskill, since such a modification would provide the delivery device with the lumen connected to a flexible implantable injection port and catheter for providing an internal access point to the device conduit.

Claims 33-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moenning, in reference of the discussion of the device of claim 1 above, in further view of Gaskill. Moenning discloses a method of treating an individual in need of therapeutic treatment which involves administration of a biological moiety, the method comprising the step of introducing the device of claim 1 into the central venous vasculature for a sufficient period to deliver a sufficient amount of said biological moiety to the individual to achieve a therapeutic effect See Paragraphs 30-39). Moenning discloses the claimed invention and method except for using it treat diabetes. Gaskill teaches that it is known to use delivery device methods to treat diabetes as set forth in paragraphs at columns 1-4 to provide to provide an effective treatment regimen. It would have been obvious to

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one having ordinary skill in the art at the time the invention was made to modify the drug delivery method as taught by Moening with a treatment for diabetes as taught by Gaskill, since such a modification would provide the drug treatment method with a treatment for diabetes for providing an effective treatment regimen for the disease.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gray whose telephone number is (571) 272-7180. The examiner can normally be reached on Monday through Friday, 8:30 a.m. to 4:30 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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C.
KEVIN SIMONS
PRIMARY EXAMINER

